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10/743,991	12/23/2003	D. Michael Connolly	201448/291	9031

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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/743,991	CONNOLLY, D. MICHAEL	
	Examiner	Art Unit	
	Samuel Woolwine	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *31-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-30* is/are rejected.

7)☒ Claim(s) *9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Claims 1-37 are pending in the application. Of these, claims 31-37 have been withdrawn as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10-19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550) in view of Butland et al (USPN 6,030,657).

With regard to claim 1, Eichen teaches:

providing a detection unit comprising one or more sets of electrically separated electrical conductor pairs (see for example page 7, lines 24-27), *each conductor having an attached capture probe such that a gap exists between the capture probes of a pair*

of electrically separated conductors (see for example page 7, lines 27-30 and figure 10A), *wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5 and figure 10A); *contacting the sample with the detection unit under conditions effective to permit any target nucleic acid present in the ... sample to bind to the capture probes, thereby connecting the capture probes* (see page 8, lines 3-6, page 41, line 18 through page 42, line 11, and figure 10A); *and detecting any target nucleic acid present in the ... sample by determining whether electricity is conducted between the electrically separated conductors* (for example, see page 8, lines 6-15).

Eichen does not teach that the target nucleic acid is used as a "taggant".

Butland teaches nucleic acid taggants for preventing product diversion and counterfeiting (see entire document, especially abstract and columns 3-5).

Butland does not teach detecting the nucleic acid taggant by a method as recited in claim 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by Eichen to detecting nucleic acids used as taggants as taught by Butland. One would have been motivated to do this because the method of Eichen represents an art-recognized means of detecting a nucleic acid target. Furthermore, Eichen teaches at the bottom of page 11 that his method is "highly sensitive, allowing the formation of a conductive bridge even where few, or even a

single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set."

With regard to claim 2, Butland teaches adding "junk DNA" to the taggant (see column 8, line 58-64).

With regard to claim 3, Eichen teaches detection of 16 μm long λ DNA (see page 41, line 18 through page 42, line 11), which "comprises" 10-30 nucleotides, since the distance between neighboring base pairs in DNA is 0.34 nm. Butland teaches DNA molecules of 80-100 base pairs in length, which "comprises 10-30 nucleotides (column 5, lines 60-61).

With regard to claim 4, Eichen teaches detecting DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 5, Eichen teaches capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen teaches capture probes which are DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 7, Butland teaches encapsulating the taggant in a matrix (e.g. casein; column 2, lines 47-54).

With regard to claim 10, Eichen teaches ligation (page 30, lines 20-23) and teaches washing at elevated temperatures to remove unbound nucleic acids and ensure high selectivity in duplex formation (page 31, lines 1-4; page 46, lines 28-30; page 55, lines 10-14).

With regard to claim 11, Eichen teaches applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20).

With regard to claim 12, Eichen teaches silver (page 41, line 12 through page 42, line 2).

With regard to claim 13, Butland teaches encapsulating the nucleic acid in a material that is resistant to the environment (column 2, lines 47-54).

With regard to claim 14, Butland teaches removal of the label for identification (column 4, line 66 through column 5, line 7).

With regard to claim 15, Butland teaches ink (column 2, lines 47-54).

With regard to claim 16, Butland teaches printing (i.e. labeling objects with an ink; column 1, line 64 through column 2, line 6).

With regard to claims 17-19, Butland teaches removing the label from a shirt, which means the taggant sample was applied to a fabric. Butland then teaches applying the taggant sample removed from the shirt to nylon. See column 5, lines 1-7.

With regard to claim 30, Eichen teaches a device having a plurality of sites for detecting different targets (see page 19, lines 11-22).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550) in view of Butland et al (USPN 6,030,657) as applied to claim 7 above and further in view of Stone (USPN 5,512,436) and McMahon et al (USPN 5,310,650).

Eichen and Butland teach of suggest all the limitations of claim 8 as discussed for claim 7 above. Furthermore, Eichen teaches addition of Denhardt's solution to the sample containing the DNA to be detected (page 54, lines 28-30). As evidenced by McMahon et al (column 9, lines 50-55), Denhardt's solution contains polyvinyl pyrrolidone and is a preferred blocking agent for hybridization assays. Stone teaches that polyethylene glycol and polyvinyl alcohol are notable examples of hybridization rate enhancers (column 3, lines 30-33).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to include compounds such as polyvinyl pyrrolidone, polyethylene glycol or polyvinyl alcohol in the matrix containing the nucleic acid taggant in the combined teachings of Eichen and Butland, since these compounds were known in the art to enhance nucleic acid hybridization, which is a critical component of the detection method taught by Eichen.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550) in view of Butland et al (USPN 6,030,657) as applied to claim 17 above and further in view of Benardelli (USPN 5,020,831).

Eichen and Butland teach or suggest the limitations of claims 24-27 as discussed for claim 17 above. They do not teach using the DNA taggant on cardboard packaging containing the item to be identified.

Benardelli teaches a method of tagging an item with a latent label for purposes such as certification and prevention of counterfeiting (see claim 1). Benardelli teaches

applying the tag to packaging (see claim 1). Benardelli teaches the package can be cardboard (column 7, lines 9-13 and figure 6; column 4, line 64 through column 5, line 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the DNA taggant taught by Butland to cardboard packaging containing the item to be identified, since Benardelli demonstrates that cardboard packaging was known in the art as a location for latent indicia for purposes of authentication and counterfeit-prevention, which is the precise purpose of the DNA taggants taught by Butland (see entire document, especially abstract and columns 3-5).

Claims 1-6, 11, 12, 15-21 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550) in view of Bancroft et al (USPN 6,312,911 B1).

With regard to claim 1, Eichen teaches:

providing a detection unit comprising one or more sets of electrically separated electrical conductor pairs (see for example page 7, lines 24-27), *each conductor having an attached capture probe such that a gap exists between the capture probes of a pair of electrically separated conductors* (see for example page 7, lines 27-30 and figure 10A), *wherein the capture probes for each pair of separated electrical conductors are complementary to one of the target nucleic acids* (see page 11, lines 3-5 and figure 10A); *contacting the sample with the detection unit under conditions effective to permit*

any target nucleic acid present in the ... sample to bind to the capture probes, thereby connecting the capture probes (see page 8, lines 3-6, page 41, line 18 through page 42, line 11, and figure 10A); *and detecting any target nucleic acid present in the ... sample by determining whether electricity is conducted between the electrically separated conductors* (for example, see page 8, lines 6-15).

Eichen does not teach that the target nucleic acid is used as a "taggant".

Bancroft teaches a method of authenticating an object by tagging it with a hidden DNA (see, for example, abstract and column 1, lines 8-15).

Bancroft does not teach detecting the DNA using a technique recited in claim 1.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to apply the nucleic acid detection method taught by Eichen to detecting nucleic acids used as taggants as taught by Bancroft. One would have been motivated to do this because the method of Eichen represents an art-recognized means of detecting a nucleic acid target. Furthermore, Eichen teaches at the bottom of page 11 that his method is "highly sensitive, allowing the formation of a conductive bridge even where few, or even a single complex between a recognition moiety and a target is formed between, or on the electrodes of an assay set."

With regard to claim 2, Bancroft teaches addition of random DNA (column 3, lines 4-18).

With regard to claim 3, Eichen teaches detection of 16 μm long λ DNA (see page 41, line 18 through page 42, line 11), which "comprises" 10-30 nucleotides, since the distance between neighboring base pairs in DNA is 0.34 nm.

With regard to claim 4, Eichen teaches detecting DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 5, Eichen teaches capture probes of 12 nucleotides each (see page 41, line 18 through page 42, line 11).

With regard to claim 6, Eichen teaches capture probes which are DNA (see page 41, line 18 through page 42, line 11).

With regard to claim 11, Eichen teaches applying a conductive material over the complex formed by the capture probes and target nucleic acid (page 8, lines 17-20).

With regard to claim 12, Eichen teaches silver (page 41, line 12 through page 42, line 2).

With regard to claims 15 and 16, Bancroft teaches ink (column 10, lines 40-45).

With regard to claims 17-21, Bancroft teaches applying the DNA taggant to tags made of paper, plastic, nitrocellulose, nylon or fabric (column 7, lines 23-27). Bancroft teaches applying the DNA taggant to articles of clothing (column 10, lines 13-15).

With regard to claims 28 and 29, Bancroft teaches using the DNA taggant to authenticate pharmaceuticals in either liquid or solid forms (column 10, lines 20-25).

With regard to claim 30, Eichen teaches a device having a plurality of sites for detecting different targets (see page 19, lines 11-22).

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichen et al (WO 99/57550) in view of Bancroft et al (USPN 6,312,911 B1) as applied to claim 21 above and further in view of Ryan (USPN 5,982,282).

Eichen and Bancroft teach or suggest the limitations of claim 22 as discussed for claim 21 above, but do not say anything about the label being tamper proof.

Ryan teaches a tamper proof device (i.e. a label) for verifying the authenticity of merchandise (see column 1, lines 5-10 and figure 1). Ryan teaches the housing of the device is molded plastic (column 2, lines 44-45). Ryan teaches the device contains a bar-code (i.e. it is a bar-code label; column 3, lines 3-13). Ryan teaches the device contains an authentication element such as DNA (column 4, lines 39-41). Ryan teaches the device is tamper proof (column 3, lines 54-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention of the instant application was made to use a tamper proof device comprising DNA as taught by Ryan in the method of verifying authenticity of an item using a DNA taggant as suggested by the combination of Eichen and Bancroft. One would have been motivated to use a tamper proof device as taught by Ryan in order to prevent a counterfeiter or other malefactor from altering or discovering the DNA taggant.

Claim Rejections - 35 USC § 103—Response to arguments

Applicant's arguments filed 3/30/2007 have been fully considered but they are not persuasive.

Applicant's arguments on page 6 of the response address the rejection over Eichen et al (WO 99/57550) in view of Butland et al (USPN 6,030,657). In the first two

paragraphs of this argument, Applicant merely asserts that the prior art does not provide or make obvious a method for rapidly screening for specific DNA taggants in complex mixtures. Applicant also cites text from the specification regarding the advantages of Applicant's invention. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Next, Applicant argues that although the Butland patent teaches DNA taggants, it does not disclose an electronic DNA reader. This argument is not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Eichen reference is relied upon to teach the electronic DNA detection device.

Appicant argues that the Eichen reference "does not disclose that the electronic detection process can be readily miniaturized" or "taken out of a laboratory setting". There is nothing in the claims regarding any state of miniaturization or where the analysis is performed.

Applicant's arguments over the rejection of claims 8 and 24-27 rely on the same arguments discussed above and are therefore also not persuasive.

Applicant's arguments directed to the rejection over Eichen et al in view of Bancroft et al (USPN 6,312,911) are presented on page 7 of the response. Applicant

argues that Bancroft does not disclose "a method which can be used to rapidly and correctly identify specific DNA sequences used as taggants". Firstly, this language is not found in the claims. Secondly, this argument amounts to attack of the individual reference (Bancroft), whereas the rejection is based on the combination of Eichen and Bancroft (see comments above regarding attacking references individually). Finally, Applicant has presented no evidence or explanation as to why the method of Eichen (which involves detection of nucleic acid sequences using an electronic device) could not be used for the "rapid accurate detection of taggant DNA".

Applicant's arguments over the rejection of claims 22 and 23 rely on the same arguments discussed above and are therefore also not persuasive.

Double Patenting—Response to arguments

The rejections under this section of the previous Office action are withdrawn in view of the terminal disclaimers filed 3/30/2007.

Allowable Subject Matter

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Eichen does not teach contacting the capture probes with nucleases after "contacting the sample with the detection unit under conditions effective to permit any target nucleic acid present in the taggant sample to bind to the capture probes, thereby connecting the capture probes". Eichen does not make any mention of a nuclease, and

there is no apparent reason to modify Eichen's method to add the step of contacting the capture probes with nucleases.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Woolwine whose telephone number is (571) 272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

scw

JEFFREY FREDMAN
PRIMARY EXAMINER
8/1/07